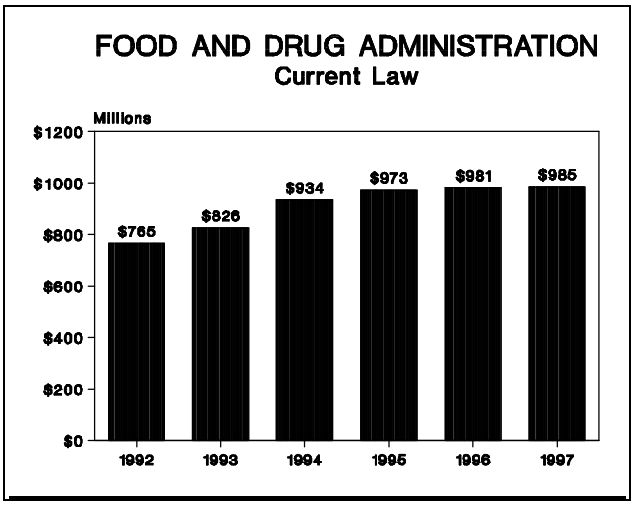
FOOD AND DRUG ADMINISTRATION

(Dollars in millions)

	1995 Actual	1996 Enacted	1997 Request	Request +/-Enacted
Current Law:				
Program Level	$973	$981	$985	+$4
Budget Authority	882	878	878	0
Outlays	860	877	881	+4
Proposed Legislation:				
Program Level		0	$39	+$39
Budget Authority		0	0	0
Outlays		0	0	0
Total, Net Proposed Law:				
Program Level	$973	$981	$1,024	+$43
Budget Authority	882	878	878	0
Outlays	860	877	881	+4
FTE	9,264	9,264	9,264	0

Summary

The FY 1997 budget request for the Food and Drug Administration (FDA) under current law is $985 million in program level spending, of which $107 million is to be derived from authorized, targeted, industry-specific user fees. In addition, FDA is proposing two new additive user fees bringing the total proposed program level spending to $1,024 million, a $43 million increase over FY 1996. Under the FY 1997 request, total budget authority will be maintained at the FY 1996 level.



Food Safety

Although the United States has the safest food supply in the world, the Centers for Disease Control and Prevention estimate that there are as many as 9,000 food-related deaths and 80 million food-related illnesses each year in this country. The annual costs for hospital stays alone related to food-borne disease are estimated to be $3.1 billion, with seafood-related illnesses costing about $144 million annually. FDA is proposing a series of Food Safety initiatives to address current concerns and to meet the safety issues the Nation is likely to face in the 21st century. A modest $4 million increase would allow FDA to expedite implementation of the new Seafood Hazard Analysis Critical Control Point (HACCP) program, expand and develop new partnerships with academia and industry to increase our food science capabilities, and use third party reviewers to improve the timeliness and efficiency of the food additive petition review process.

Prescription Drug User Fees

The Prescription Drug User Fee Act (PDUFA), first implemented in 1993, has been highly successful in enabling FDA to significantly accelerate approval of safe and effective human drugs. FDA has met or exceeded all of the Act's performance goals to date. Already, FDA has achieved one of the major 1997 performance goals in FY 1994--a full three years ahead of schedule. For the drugs submitted to FDA in FY 1994, FDA reviewed and acted upon 96 percent of them on time. In most cases, that meant action within 12 months. The backlog of overdue applications has been eliminated. To sustain momentum toward reaching the final performance goals in FY 1997, the FY 1997 budget includes $87.5 million in user fees, a 7 percent increase. This will provide for additional review staff, bringing FDA to a total PDUFA staffing increase of 700 FTE.

Mammography Quality Standards Act

FDA will continue to implement the Mammography Quality Standards Act to assure that women receive quality mammography from facilities that maintain a high standard of safety and accuracy. In FY 1997, FDA will focus its energies on ensuring that all facilities are meeting the quality standards for mammography and that identified deficiencies are corrected. By the end of FY 1996, for the first time, certified personnel will have inspected over 10,000 facilities in all. During FY 1997, FDA will fund 10,000 annual inspections and will conduct 3,000 facility recertifications. To achieve these goals, the FDA request includes $26 million for implementing the Mammography Quality Standards Act, of which $13 million is to be collected in fees from inspected facilities, as authorized by the Act.

Proposed New User Fees

In FY 1997, FDA is requesting authority to implement two new user fee activities totalling $39 million. Of these fees, $24 million is to accelerate the medical device approval process and $15 million is to improve the effectiveness and efficiency of its imported products regulatory compliance program. FDA is proposing to incorporate the concepts embodied in

the highly effective Prescription Drug User Fee Act into the medical devices field to eliminate the current backlog and to reduce the time it takes to approve medical device applications. The user fee goal is to increase the percentage of pre-market notification (510-(k)) applications completed within 90 days from 50 percent in FY 1995 to 90 percent in FY 1997, and pre-market approval applications completed within 180 days from 44 percent in FY 1995 to 75 percent in FY 1997. The new import user fee will provide FDA the resources necessary to substantially reduce the risk posed by potentially harmful foods and other products that reach the American marketplace through import channels.

FDA OVERVIEW

(Dollars in millions)

	1995 Actual	1996 Enacted	1997 Request	Request +/-Enacted
Current Law:				
Salaries & Expenses:				
Foods	$215	$222	$226	+$4
Drugs	445	446	449	+3
Medical Devices	166	170	170	0
National Center for Toxicological Research	35	38	38	0
Program Management	43	42	42	0
Subtotal, Salaries & Expenses	$904	$918	$925	+$7
GSA Rental Payments	46	46	46	0
Buildings & Facilities	18	12	8	-4
Revolving Fund	5	5	6	+1
Subtotal, Program Level	$973	$981	$985	+$4
Less User Fees:				
Prescription Drugs	$79	$85	$88	+$3
Mammography Inspection	7	13	13	0
Revolving Fund	5	5	6	+1
Subtotal, User Fees	$91	$103	$107	+$4
Total, BA	$882	$878	$878	0
Proposed Law:				
User Fees:				
Medical Devices		*$0*	*$24*	*+$24*
Import Inspection		*0*	*15*	*+15*
Subtotal, User Fees		*$0*	*$39*	*+$39*
Total, Program Level	*$973*	*$981*	*$1,024*	*+$43*
FTE	9,264	9,264	9,264	0